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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,524	08/15/2001	Andrew N. Shelling	3911-10	9590

7590

12/03/2002

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,524

Applicant(s)

SHELLING, ANDREW N.

Examiner

Diana B. Johansen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

ELECTION/RESTRICTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to methods of detecting predisposition to premature ovarian failure (POF).

Group II, claim(s) 11-12, drawn to methods of treating POF using nucleic acids.

Group III, claim(s) 11 and 13, drawn to methods of treating POF using polypeptides.

Group IV, claim(s) 14, drawn to use of a polypeptide in manufacture of a pharmaceutical composition.

2. It is noted that claim 11 has been presented in improper format, as the claim encompasses two types of treatment methods (methods employing nucleic acids and methods employing polypeptides) that lack unity of invention with one another, for the reasons set forth below. The claim has been included in multiple groups (Group II and Group III), and if either of these groups is elected, will be examined only to the extent that it is drawn to the elected invention.

3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The inventions of Groups I-III share a technical feature in that the claims require determination of an "alteration in the gene encoding inhibin" that is "indicative of a

predisposition to POF" (see claim 1). Group IV shares a technical feature with Groups I-III in that claim 14 encompasses the use of inhibin in preparation of a medicament for treating POF. However, the claims of Group I are sufficiently broad so as to encompass methods in which one determines the presence or absence of an alteration by "comparing the level of expression and/or activity of inhibin protein present in a sample" from a subject with levels of expression/activity of "wild-type inhibin protein" (see, e.g., claim 9). The prior art as exemplified by Petraglia et al (Fertility and Sterility 70(5):907-912 (9/1998), abstract only) discloses methods comprising comparing levels of inhibin A and inhibin B in the blood of women with POF with inhibin levels in age-matched controls, and teach that "low levels of circulating inhibins A and B....reflect ovarian failure in women with POF" (see entire reference). Accordingly, a relationship between alteration in levels of expression of inhibin and POF were known in the art at the time the invention was made. As the technical feature linking Groups I-IV does not make a contribution over the art, this feature cannot constitute a special technical feature within the meaning of PCT Rule 13.2. Further, Groups I-IV do not share another technical feature that could constitute a special technical feature as defined by PCT Rule 13.2. The steps to accomplish detection of Groups I-III (e.g., methods of sequencing, restriction digestion, etc.) are well known in the art. The step of supplying nucleic acids of Group II is not shared by Groups I and III-IV. The step of supply polypeptides of Group III is not shared by Groups I-II and IV. The use of inhibin in preparation of a composition of Group IV is not shared by Groups I-III. Further, Groups I, II-III, and IV have different objectives and effects. Accordingly, unity of invention is lacking.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in cursive script, appearing to read "Diana B. Johannsen", followed by a long horizontal flourish.

Diana B. Johannsen
December 2, 2002